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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,034	01/30/2004	Kameswari S. Konduri	KSKO-25,661	7598

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,034	KONDURI ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Examiner Notes

Claims 8 and 25 are self-referential. Amendment to claim language is suggested. Furthermore, Claim 28 is absent.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4, 21, 23, 37 and 39, drawn to a method for treating a respiratory tract of a mammal by aerosol administration of an effective amount of a composition comprising a sterically stabilized liposome carrier consisting of phosphatidylcholine and phosphatidylglycerol in combination with a drug, classified in class 424, subclass 450.

II. Claims 7-8, 24-25 and 40-41, drawn to a method for treating a respiratory tract of a mammal by aerosol administration of an effective amount of a composition comprising a sterically stabilized liposome carrier consisting of phosphatidylcholine and polyethylene glycol in combination with a drug, classified in class 424, subclass 450.

III. Claims 12, 29 and 45, drawn to a method for treating a respiratory tract of a mammal by aerosol administration of an effective amount of a composition comprising a sterically stabilized liposome carrier consisting of at least one of six specific combinations of compounds in combination with a drug, classified in class 424, subclass 450.

IV. Claims 13, 30 and 46, drawn to a method for treating a respiratory tract of a mammal by aerosol administration of an effective amount of a composition comprising a sterically stabilized liposome carrier consisting of a at least one of four specific combinations of compounds in combination with a drug, classified in class 424, subclass 450.

Claims 1-3, 5-6, 9-11, 14-15, 18-20, 22, 26-27, 31-32, 35-36, 38, 42-44, 47-48 and 51-52 link Groups I-IV.

Claims 16 and 33 link Groups I, II and IV.

Claims 17, 34 and 49-50 link Groups I and IV.

Claims 1-3, 5-6, 9-11, 14-15, 18-20, 22, 26-27, 31-32, 35-36, 38, 42-44, 47-48 and 51-52 link Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 1-3, 5-6, 9-11, 14-15, 18-20, 22, 26-27, 31-32, 35-36, 38, 42-44, 47-48 and 51-52.

Claims 16 and 33 link Groups I, II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 16 and 33.

Claims 17, 34 and 49-50 link Groups I and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 17, 34 and 49-50.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, while each composition comprises a sterically stabilized liposome, each specified carrier molecule formulation is materially and structurally distinct from the others and confers distinctly different properties and effects on the liposome and its ability to interact with the target cell membrane. The carrier groups are essential inventive features of the sterically stabilized liposome, directly affecting the phase transition temperature and the bioavailability of the liposome. The distinctive carrier properties increase in complexity and uniqueness when non-obvious carrier compound subcombinations are intentionally combined into a final liposome composition.

Given that the intended use of the liposome carrier is to be compatible with a mammalian respiratory tract and to extend the effective life of a drug in the respiratory tract, the search and examination burden for all the different possible carrier compound combinations claimed to fulfill the recited functional requirements is exceptional. A search for phosphatidylinositol would not be co-extensive with a search for lipid-conjugated polysorbate. A reference rendering polyethylene glycol as anticipated or obvious over the prior art would not necessarily also render a lipid as anticipated or obvious over the prior art. Similarly, a finding that phosphatidylglycerol was novel and unobvious over the prior art would not necessarily extend to a finding that polyethylene glycol-distearoylphosphatidyldiethanolamine with cholesterol was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

2. **Should Applicant elect any of Inventions I-IV**, a group restriction is required under 35 U.S.C. 121. Applicant is required to elect a single disclosed acyl group combination from the list of carriers recited specifically in Claims 9-11, 26-27, 42-44 for prosecution on the merits to which the claims shall be restricted. In the instant case, each acyl group is structurally distinct and confers distinctly different properties on the liposome carrier group. The specification

teaches (page 6, lines 13-15 and page 8, lines 16-23) that the acyl groups are an essential inventive feature of the sterically stabilized liposome and directly affect the bioavailability of the liposome. A reference rendering a distearoyl as anticipated or obvious over the prior art would not necessarily also render plamitoyl oleoyl as anticipated or obvious over the prior art. Because a search of one acyl group combination does not necessarily overlap with that of another acyl group combination, it would be unduly burdensome for the examiner to search and examine all the acyl group combinations being sought in the presently pending claims for the reasons given above and thus, restriction for examination purposes as indicated.

Should Applicant elect Invention III, a further group restriction is required under 35 U.S.C. 121. Applicant is required to elect a single disclosed carrier combination from the list of carriers recited specifically in Claims 12, 29 and 45 for prosecution on the merits to which the claims shall be restricted.

Should Applicant elect Invention IV, a further group restriction is required under 35 U.S.C. 121. Applicant is required to elect a single disclosed carrier combination from the list of carriers recited specifically in Claims 13, 30 and 46 for prosecution on the merits to which the claims shall be restricted.

The carrier groups of Inventions III and IV are distinct for the same reasons given above. The carrier groups are essential inventive features of the sterically stabilized liposome, directly affecting the phase transition temperature and the bioavailability of the liposome. Because a search of one carrier combination does not necessarily overlap with that of another carrier combination, it would be unduly burdensome for the examiner to search and examine all the carrier combinations being sought in the presently pending claims for the reasons given above and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed carrier combination for Inventions III and IV, even though this requirement is traversed. Failure to elect a specific carrier combination for Inventions III and IV consonant with Applicant's elected Invention, may result in a notice of non-responsive amendment.

Should Applicant elect any of Inventions I-IV, further group restriction is required under 35 U.S.C. 121. Claim(s) 1-2, 14, 18-19, 35 and 47 are generic to a drug. Applicant is required to elect a single drug group, wherein illustrative drugs are recited specifically in Claim(s) 5-6, 15, 32, 48 and 51-52 for prosecution on the merits to which the claims shall be restricted. Therefore, election is required of any of Inventions I-V and one of the inventive drug groups (a)-(f) as described in Claims 15, 32 and 48.

a) corticosteroids

b) bronchodilators,

c) leukotriene inhibitors,

d) antihistamines,

e) antibiotics,

f) serine lung protease inhibitors,

The inventive drug groups (a)-(f) are distinct because,

The drugs of inventive drug groups (a)-(f) are unrelated. Each drug is materially and structurally distinct, and confers distinctly different properties and effects on the target cell. Furthermore, each drug is independent and mutually exclusive of the others. A reference rendering a corticosteroid as anticipated or obvious over the prior art would not necessarily also render an antibiotic as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed drug, even though this requirement is traversed. Failure to elect a drug from Inventions I-V, inventive drug groups (a)-(f) above consonant with any of Applicant's elected Invention, may result in a notice of non-responsive amendment.

3. **Should Applicant elect any of Inventions I-IV** and any one of drug groups (a)-(f) above, a species restriction is required under 35 U.S.C. 121. Currently, Claims 1, 18 and 35 of this application are generic to a plurality of disclosed, patentably distinct drug compounds that prohibit proper examination of this claim (see Claim 15, for example). Applicant is required under 35 U.S.C. 121 to elect one drug group (a)-(f) above and a single disclosed species from within the elected drug group in each claim for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the instant case, each drug species is materially and structurally distinct, as each drug confers distinctly different properties and effects on the target cell, and each drug is independent and mutually exclusive of the others. A search for terbutaline would not be co-extensive with a search for formoterol. A reference rendering montelukast as anticipated or obvious over the prior art would not necessarily also render zileuton as anticipated or obvious over the prior art. Similarly, a finding that rifamycin was novel and unobvious over the prior art would not necessarily extend to a finding that ciprofloxacin was also novel and unobvious over the prior art.

Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER